

## REMARKS

This Paper is submitted in response to the Office Action dated December 27, 2006 having a shortened statutory response period ending on March 27, 2007. This Paper is submitted within the shortened statutory response period. The Commissioner is hereby authorized to any additional fees to Deposit Account number 02-1818.

Claims 1-21 and 23-53 are currently pending in this application. Claims 22 and 54-120 have been canceled.

Claims 1-21, 23-34, and 48-53 were rejected under 35 U.S.C. §103(a) for allegedly being obvious over U.S. Patent No. 5,935,847 to Smith et al. (*Smith*) in view of U.S. Patent No. 6,759,245 to Toner et al. (*Toner*). Claims 36-46 were rejected under 35 U.S.C. § 103(a) over *Smith* in view of *Toner* and in further view of U.S. Patent No. 5,989,215 to Delmotte (*Delmotte*). Applicants respectfully disagree with and traverse these alleged rejections for the reasons set forth below.

*Smith*, *Toner*, and *Delmotte*, either alone or in combination, do not disclose or suggest a closed support container having opposing flexible exterior sidewalls, at least one of the sidewalls being gas permeable, with a fibrin matrix layer on a portion of an interior sidewall surface as recited in the present claims. *Smith* has no disclosure whatsoever regarding fibrin, let alone a container having a fibrin layer. In fact, the Examiner has admitted the same. See Office Action dated July 27, 2006 at ¶ 1.

*Toner* fails to fulfill this deficiency of *Smith*. The Examiner states that *Toner* is relied upon only for the teaching that a fibrin matrix may be used to accommodate cell growth. Office Action dated December 27, 2006 at pp. 9-10 (“The Toner reference is only relied upon for its teachings regarding the merits of using a fibrin matrix layer to accommodate growing cells”). Applicants respectfully submit that *Toner* is merely cumulative with respect to the knowledge that fibrin may be used as a cell growth substrate. The ability of a fibrin matrix to support cell growth is known in the art. See present application, page 3 line 23 through page 4 line 2 (coating a polymeric material with fibrin is known in the art). As it is known in the art to use a fibrin matrix to support cell growth, the Examiner’s reliance on *Toner*’s disclosure of a fibrin matrix as a cell growth substrate is cumulative.

The Examiner further states that “[t]he Toner reference is in no way relied upon for its teaching regarding the polymer construction of the container sidewalls.” Office Action dated

December 27, 2006 at page 9. Applicants respectfully disagree with the Examiner's position. As fibrin is known to be a cell growth substrate, the threshold issue with respect to *Toner* is the disclosure regarding the structure of the cartridges for the bioreactor 1.

A reference must be viewed as a whole for what it reasonably discloses. *In re Wright*, 6 USPQ2d 1959 (Fed. Cir. 1988). Thus, when *Toner* is properly viewed as a whole for what it reasonably discloses, it is clear that *Toner* teaches away from a closed support container having flexible and gas permeable exterior sidewalls and a fibrin layer on an interior sidewall surface as recited in the present claims. *Toner* discloses a bioreactor having a cartridge. A polymeric membrane 30 (which may be coated with fibrin) defines two chambers in the cartridge. The cartridge includes rigid and impermeable exterior walls 50. *Toner*, col. 2 lines 39-45, col. 7 lines 38-59, col. 11 lines 27-41 ("rigid impermeable walls 50"). As *Toner* discloses a cartridge having impermeable and rigid exterior walls, *Toner* teaches away from the support container having flexible and gas permeable exterior sidewalls as recited in the present claims.

*Toner* further teaches away from a closed container as recited in the present claims. *Toner* discloses a flow-through cell-culturing device. *Toner*, col. 2 lines 35-50. *Toner's* cartridge includes oxygenated fluid inlet/out 3,3' and liquid inlet/outlet 5,5'. The inlets and outlets permit continuous fluid flow through *Toner's* cartridge. The inlets and outlets fulfill an object of *Toner* which is to cultivate cells on membrane 30 by passing flowing fluid along each side of the membrane 30. *Toner*, col. 2 lines 35-45. Accordingly, *Toner's* flow-through cartridge is an open system, not a closed system. *Toner's* open, flow-through cell-culturing device therefore teaches away from the closed support container recited in the present claims. Teaching away is a *per se* demonstration of non-obviousness. *In re Dow Chemical Co.*, 837 F.2d 469 (Fed. Cir. 1988). Consequently, any combination of *Toner* with *Smith* and/or *Delmotte* is likewise *per se* non-obvious.

The Examiner's reliance on one aspect of *Toner* which is already known in the art while ignoring other teaching away aspects of *Toner* is a strong indication that the Examiner is using Applicants' disclosure as a blueprint to pick and choose from isolated portions of the prior art in order to deprecate Applicants' claims. Such conduct is exemplary of hindsight reasoning. Hindsight is improper as a matter of law. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

*Delmotte* also teaches away from a closed support container having flexible and gas permeable exterior sidewalls as recited in the present claims. *Delmotte* discloses a fibrin

delivery device 10 having first and second syringes 12, 14 and a spray unit 18. A pressurizer 22 travels through each syringe 12, 14 to push fluid present in each syringe through the spray unit 18. *Delmotte*, col. 8 lines 31-43, col. 9 lines 47-58, Figures 1 and 4. One of ordinary skill in the art would recognize that syringes 12, 14 are rigid in order to withstand the pressure imposed by pressurizer 22 when pushing fluid out of each syringe. *Delmotte's* rigid syringes teach away from the supporting container having flexible exterior sidewalls as recited in the present claims.

In summation, *Smith* has no disclosure of a cell culture container having a fibrin layer as admitted by the Examiner. *Toner* and *Delmotte* each individual teach away from the claimed support container having flexible exterior sidewalls.

### **CONCLUSION**

In view of the foregoing remarks, Applicants submit that claims 1-21 and 23-53 are in a condition for allowance and respectfully request a notice of the same.

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